

AMENDMENTS TO THE CLAIMS

Claims 1-153 canceled.

154. (New) A method for forming a flocculated suspension of megestrol acetate, comprising the following steps:

preparing a wetting agent composition by combining a wetting agent, a suspending agent and optionally other ingredients,

combining micronized megestrol acetate and optionally other ingredients with the wetting agent composition,

optionally performing additional steps or adding additional ingredients,

wherein one or more of the steps is performed at a temperature of at least about 25C,

wherein about 90% of the floccules of megestrol acetate have a diameter of less than 12 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

155. (New) The method of claim 154, wherein about 90% of the floccules have a diameter of less than 21 to 50 microns.

156. (New) The method of claim 154, wherein about 90% of the floccules have a diameter of less than 28 to 50 microns.

157. (New) The method of claim 154, wherein the temperature is above 25C.

158. (New) The method of claim 154, wherein the temperature is above 30C.

159. (New) The method of claim 154, wherein the temperature is above 55C.

160. (New) The method of claim 154, wherein the temperature is between about 55C and 75C.

161. (New) The method of claim 154, wherein the wetting agent comprises docusate sodium.

162. (New) The method of claim 154, wherein the wetting agent comprises a polyoxyethylene wetting agent.

163. (New) The method of claim 161, wherein the docusate sodium is present in the flocculated suspension in an amount of about 0.01 to about 0.04% w/w.

164. (New) The method of claim 154, wherein the suspending agent comprises a polyhydric alcohol.

165. (New) The method of claim 154, wherein the suspending agent comprises a hydrocolloid material.

166. (New) The method of claim 154, wherein the hydrocolloid material comprises a material selected from the group consisting of xanthum gum, hydroxypropyl cellulose, and carboxymethyl cellulose.

167. (New) The method of claim 154, wherein the suspending agent comprises xanthum gum.

168. (New) The method of claim 154, wherein the optional ingredients comprise a buffer.

169. (New) The method of claim 154, wherein the buffer comprises a material selected from the group consisting of sodium citrate and citric acid.

170. (New) The method of claim 154, wherein the optional ingredients comprise a preservative.

171. (New) The method of claim 170, wherein the preservative is sodium benzoate.

172. (New) The method of claim 154, wherein megestrol acetate is present in the flocculated suspension in an amount of about 40 mg/ml.

173. (New) The method of claim 154, further comprising using high shear mixing for one or more of the steps.

174. (New) The method of claim 173, wherein the mixing occurs for at least one hour.

175. (New) The method of claim 173, wherein the mixing occurs at a temperature of about 55 to about 75C.

176. (New) The method of claim 173, wherein the mixing is performed under vacuum.

177. (New) The method of claim 154, wherein the suspending agent is added through the bottom of a vessel containing the wetting agent.

178. (New) The method of claim 154, further comprising cooling the wetting agent composition.

179. (New) The method of claim 178, further comprising mixing while cooling.

180. (New) The method of claim 178, wherein cooling is continued down to about 25C.

181. (New) The method of claim 178, further comprising cooling the wetting agent composition to a temperature of about 25 to about 30C.

182. (New) The method of claim 178, wherein the megestrol acetate is combined with the cooled wetting agent composition.

183. (New) The method of claim 154, further comprising adjusting batch weight with water.

184. (New) The method of claim 183, further comprising adjusting the batch weight to about 40 mg megestrol acetate per ml.

185. (New) The method of claim 154, further comprising screening the combined megestrol acetate and wetting agent composition.

186. (New) The method of claim 154, further comprising straining the combined megestrol acetate and wetting agent composition.

187. (New) The method of claims 154, wherein the megestrol acetate is combined with the wetting agent composition at a pressure of about 7 to about 10 psi.

188. (New) A method for forming a flocculated suspension of megestrol acetate, comprising the following steps:

preparing a wetting agent composition by combining a wetting agent, a suspending agent and optionally other ingredients,

combining micronized megestrol acetate and optionally other ingredients with the wetting agent composition,

optionally performing additional steps or adding additional ingredients,

wherein one or more of the steps uses high shear mixing for at least about one hour,

wherein about 90% of the floccules of megestrol acetate have a diameter of less than 12 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

189. (New) The method of claim 188, wherein about 90% of the floccules have a diameter of less than 21 to 50 microns.

190. (New) The method of claim 188, wherein about 90% of the floccules have a diameter of less than 28 to 50 microns.

191. (New) The method of claim 188, wherein one or more of the steps is performed at a temperature of at least about 25C.

192. (New) The method of claim 188, wherein the temperature is about 25C.

193. (New) The method of claim 188, wherein the temperature is above 30C.

194. (New) The method of claim 188, wherein the temperature is above 55C.

195. (New) The method of claim 188, wherein the temperature is between about 55C and 75C.

196. (New) The method of claim 188, wherein the wetting agent comprises docusate sodium.

197. (New) The method of claim 188, wherein the wetting agent comprises a polyoxyethylene wetting agent.

198. (New) The method of claim 196, wherein the docusate sodium is present in the flocculated suspension in an amount of about 0.01 to about 0.04% w/w.

199. (New) The method of claim 188, wherein the suspending agent comprises a polyhydric alcohol.

200. (New) The method of claim 188, wherein the suspending agent comprises a hydrocolloid material.

201. (New) The method of claim 200, wherein the hydrocolloid material comprises a material selected from the group consisting of xanthum gum, hydroxypropyl cellulose, and carboxymethyl cellulose.

202. (New) The method of claim 188, wherein the suspending agent comprises xanthum gum.

203. (New) The method of claim 188, wherein the optional ingredients comprise a buffer.

204. (New) The method of claim 203, wherein the buffer comprises a material selected from the group consisting of sodium citrate and citric acid.

205. (New) The method of claim 188, wherein the optional ingredients comprise a preservative.

206. (New) The method of claim 205, wherein the preservative is sodium benzoate.

207. (New) The method of claim 188, wherein megestrol acetate is present in the flocculated suspension in an amount of about 40 mg/ml.

208. (New) The method of claim 188, wherein the mixing occurs for about one hour.

209. (New) The method of claim 188, wherein the mixing occurs at a temperature of about 55 to about 75 °C.

210. (New) The method of claim 188, wherein the mixing is performed under vacuum.

211. (New) The method of claim 188, wherein the suspending agent is added through the bottom of a vessel containing the wetting agent.

212. (New) The method of claim 188, further comprising cooling the wetting agent composition.

213. (New) The method of claim 212, further comprising mixing while cooling.

214. (New) The method of claim 212, wherein cooling is continued down to about 25 °C.

215. (New) The method of claim 212, further comprising cooling the wetting agent composition to a temperature of about 25 to about 30 °C.

216. (New) The method of claim 212, wherein the megestrol acetate is combined with the cooled wetting agent composition.

217. (New) The method of claim 188, further comprising adjusting batch weight with water.

218. (New) The method of claim 217, further comprising adjusting the batch weight to about 40 mg megestrol acetate per ml.

219. (New) The method of claim 188, further comprising screening the combined megestrol acetate and wetting agent composition.

220. (New) The method of claim 188, further comprising straining the combined megestrol acetate and wetting agent composition.

221. (New) The method of claims 188, wherein the megestrol acetate is combined with the wetting agent composition at a pressure of about 7 to about 10 psi.

222. (New) A method for forming a flocculated suspension of megestrol acetate, comprising the following steps:

preparing a wetting agent composition by combining a wetting agent, a suspending agent and optionally other ingredients,

combining micronized megestrol acetate and optionally other ingredients with the wetting agent composition,

optionally performing additional steps or adding additional ingredients,

wherein the batch weight is adjusted to achieve about 40 mg megestrol acetate per ml,

wherein about 90% of the floccules of megestrol acetate have a diameter of less than 12 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

223. (New) The method of claim 222, wherein about 90% of the floccules have a diameter of less than 21 to 50 microns.

224. (New) The method of claim 222, wherein about 90% of the floccules have a diameter of less than 28 to 50 microns.

225. (New) The method of claim 222, wherein one or more of the steps is performed at a temperature of at least about 25C.

226. (New) The method of claim 222, wherein the temperature is about 25C.

227. (New) The method of claim 222, wherein the temperature is above 30C.

228. (New) The method of claim 222, wherein the temperature is above 55C.

229. (New) The method of claim 222, wherein the temperature is between about 55C and 75C.

230. (New) The method of claim 222, wherein the wetting agent comprises docusate sodium.

231. (New) The method of claim 222, wherein the wetting agent comprises a polyoxyethylene wetting agent.

232. (New) The method of claim 230, wherein the docusate sodium is present in the flocculated suspension in an amount of about 0.01 to about 0.04% w/w.

233. (New) The method of claim 222, wherein the suspending agent comprises a polyhydric alcohol.

234. (New) The method of claim 222, wherein the suspending agent comprises a hydrocolloid material.

235. (New) The method of claim 234, wherein the hydrocolloid material comprises a material selected from the group consisting of xanthum gum, hydroxypropyl cellulose, and carboxymethyl cellulose.

236. (New) The method of claim 222, wherein the suspending agent comprises xanthum gum.

237. (New) The method of claim 222, wherein the optional ingredients comprise a buffer.

238. (New) The method of claim 237, wherein the buffer comprises a material selected from the group consisting of sodium citrate and citric acid.

239. (New) The method of claim 222, wherein the optional ingredients comprise a preservative.

240. (New) The method of claim 239, wherein the preservative is sodium benzoate.

241. (New) The method of claim 222, wherein megestrol acetate is mixed into the wetting agent composition .

242. (New) The method of claim 241, wherein the mixing occurs for at least one hour.

243. (New) The method of claim 241, wherein the mixing occurs at a temperature of about 55 to about 75C.

244. (New) The method of claim 241, wherein the mixing is performed under vacuum.

245. (New) The method of claim 222, wherein the suspending agent is added through the bottom of a vessel containing the wetting agent.

246. (New) The method of claim 222, further comprising cooling the wetting agent composition.

247. (New) The method of claim 246, further comprising mixing while cooling.

248. (New) The method of claim 246, wherein cooling is continued down to about 25C.

249. (New) The method of claim 246, further comprising cooling the wetting agent composition to a temperature of about 25 to about 30C.

250. (New) The method of claim 246, wherein the megestrol acetate is combined with the cooled wetting agent composition.

251. (New) The method of claim 222, further comprising adjusting batch weight with water.

252. (New) The method of claim 251, further comprising adjusting the batch weight to about 40 mg megestrol acetate per ml.

253. (New) The method of claim 222, further comprising screening the combined megestrol acetate and wetting agent composition.

254. (New) The method of claim 222, further comprising straining the combined megestrol acetate and wetting agent composition.

255. (New) The method of claims 222, wherein the megestrol acetate is combined with the wetting agent composition at a pressure of about 7 to about 10 psi.

256. (New) The method of claim 222, further comprising using high shear mixing for one or more of the steps.

257. (New) The method of claim 256, wherein the mixing occurs for at least one hour.

258. (New) The method of claim 222, wherein the wetting agent composition comprises at least a polyhydric alcohol, docusate sodium, and xantham gum.

259. (New) The method of claim 154, wherein additional steps include the addition of sodium citrate, citric acid and sodium benzoate.

260. (New) The method of claim 154, wherein the wetting agent composition comprises at least a polyhydric alcohol, docusate sodium, and xantham gum.

261. (New) The method of claim 188, wherein additional steps include the addition of sodium citrate, citric acid and sodium benzoate.

262. (New) The method of claim 188, wherein the wetting agent composition comprises at least a polyhydric alcohol, docusate sodium, and xantham gum.

263. (New) The method of claim 222, wherein additional steps include the addition of sodium citrate, citric acid and sodium benzoate.

264. (New) The method of claim 222, wherein the wetting agent composition comprises at least a polyhydric alcohol, docusate sodium, and xantham gum.